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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/049,967

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James Oliver Dolly

17790(BOT)

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EXAMINER

ARCHIE, NINA

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

07/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/049,967	Applicant(s) DOLLY ET AL.	
	Examiner Nina A. Archie	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48,50,53-55,57-60,62,69,70,73,75,104 and 105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,50,53-55,57-60,62,69,70,73, and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 4-10-08. Claims 48, 50, 53-60, 62, 69-70, 73, 75 and 104-105 are pending. Claims 1-47, 49, 51-52, 56, 61, 63-68, 71-72, 74, and 76-103 have been cancelled.

Rejections Withdrawn

2. In view of the Applicant's amendment and remark following objections are withdrawn.
- a) Rejection to claims 48, 50, 53-55, 57-60, and 62 under 35 U.S.C. 102(b) is withdrawn in light of applicant's amendment thereto.
 - b) Rejection to claims 48, 50 and 69-70 under 35 U.S.C. 103(a) is withdrawn in light of applicant's amendment thereto.

Claim Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 48, 50, 53-55, 57-60, 62, 69-70, 73 and 75 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons set forth in the previous office action. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's Arguments:

Claim 48 and 50 amendment support directed towards a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 that is a SNAP-25b variant having at least 95% identity to SEQ ID NO: 42 can be found throughout the present specification, such as, e.g., p. 19, line 28 though p. 20, line 6; and FIG. 8.

Currently amended Claims 48 and 50 are now directed, in part, toward a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 that is a SNAP-25b variant having at least 95% identity to SEQ ID NO: 42. Therefore, the Applicants submit that the present specification provides adequate written description support for all claims and respectfully request withdrawal of the 35 U.S.C. § 112, I[1] written description rejection against Claims 48, 50, 53-55, 57-60, 62, 69, 70, 73, and 75.

Examiner's Response to Applicant's Arguments:

Examiner accepts Applicant's amendments. However Applicant's arguments are not deemed persuasive. Claims 48 and 50 are directed to a method, administering as set forth supra SNAP-25 is a SNAP 25b variant having at least comprising a sequence at least 95% identical to SEQ ID NO: 42 and that is capable of supporting Ca^{2+} mediated exocytosis, but is resistant to proteolysis by the clostridial toxin. As discussed by Applicant, the specification discloses that it is particularly preferred if the SNAP-25 variant has an amino acid sequence which has at least 45% identity with the amino acid sequence of mouse SNAP-25b, for example the amino acid sequence of mouse SNAP-25b as given in Bark & Wilson (1994) Gene 139, 291-292 or human SNAP-25b as shown in Figure 8, more preferably at least 50%, 55 %, 60%, 65 %, 70%, still more preferably at least 75%, yet still more preferably at least 80%, in further preference at least 85%, in still further preference at least 90 % and most preferably at least 95 % or 97 % identity with the amino acid sequence defined above (see specification, e.g., p. 19, line 28 though p. 20, line 6).

The specification discloses the reduction to practice of one species within the claimed genus; specifically, the protein having the amino acid sequence of SEQ ID NO: 42. There are no drawings or structural formulas disclosed of any other proteins that that is capable of supporting Ca^{2+} mediated exocytosis, but is resistant to proteolysis by the clostridial toxin (functional limitation of the claimed invention). The recitation of a

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polypeptide with at least 95% amino acid sequence identity to SEQ ID NO: 42 represent a partial structure. That is, the claimed proteins share at least 95% of the structure of SEQ ID NO: 42, while 5% of the structure can vary. There is no teaching in the specification regarding which 5% of the structure can be varied while retaining the ability of the protein that is capable of supporting Ca^{2+} mediated exocytosis, but is resistant to proteolysis by the clostridial toxin. Further, there is no art-recognized correlation between any structure (other than SEQ ID NO: 42) and the activity of that is capable of supporting Ca^{2+} mediated exocytosis, but is resistant to proteolysis by the clostridial toxin, based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 42 without losing the functional limitation, the capability of supporting Ca^{2+} mediated exocytosis, but is resistant to proteolysis by the clostridial toxin. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 42 in the claimed genus of proteins and still retain the catalytic activity. Although the disclosure of SEQ ID NO: 42 combined with the knowledge in the art, would put one in possession of proteins that are at least 95% identical to SEQ ID NO: 42, the level of skill and knowledge in the art is such that one of ordinary skill would not be able to identify without further testing which of those proteins having at least 95% identity to SEQ ID NO: 42 (if any) have the activity that is capable of supporting Ca^{2+} mediated exocytosis, but is resistant to proteolysis by the clostridial toxin. Based on the lack of knowledge and predictability in the art, those of ordinary skill in the art would not conclude that the applicant was in possession of the claimed genus of proteins based on disclosure of the single species of SEQ ID NO: 42. Therefore the specification fails to satisfy the written description requirement requirement and the rejection has been maintained. (Please see Revision 1 March 25, 2008 Written Description Training Material specifically example PUBLISHED WRITTEN DESCRIPTION EXAMPLES specifically Example 10: Product Claimed By it Function).

Conclusion

Status of the Claims

4. No claims are allowed.

Claims 48, 50, 53-55, 57-60, 62, 69-70, 73 and 75 are rejected.

Claims 104-105 are free of the art.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1645
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GAU 1645
REM 3B31

**/Mark Navarro/
Primary Examiner, Art Unit 1645**